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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/800,541	03/07/2001	Liselotte Bjerre Knudsen	6169.200-US	4130
23650	7590	07/28/2006	EXAMINER	
NOVO NORDISK, INC. PATENT DEPARTMENT 100 COLLEGE ROAD WEST PRINCETON, NJ 08540			ROMEO, DAVID S	
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 07/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/800,541	<b>Applicant(s)</b> KNUDSEN, LISELOTTE BIERRE	
	<b>Examiner</b> David S. Romeo	<b>Art Unit</b> 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 26-29 and 36-76 is/are pending in the application.
- 4a) Of the above claim(s) 75 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26-29, 36-74 and 76 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 26-29 and 36-76 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>0406.0706</u> . | 6) <input type="checkbox"/> Other: ____.  |

### DETAILED ACTION

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 04/13/2006 has been entered.

Claims 26–29 and 36–76 are pending.

### *Election/Restrictions*

Applicant's have elected group I, claims 26–29 and 36–42, and the species Arg<sup>34</sup>,Lys<sup>26</sup>(N<sup>ε</sup>-(γ-Glu(N<sup>α</sup>-hexadecanoyl)))GLP-1(7-37) in the paper filed 11/08/2002. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 26–29 and 36–76 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) to the extent that they are drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/08/2002.

Claims 26–29 and 36–74, and 76 are being examined to the extent that are directed to, encompass, or read on the species Arg<sup>34</sup>,Lys<sup>26</sup>(N<sup>ε</sup>-(γ-Glu(N<sup>α</sup>-hexadecanoyl)))GLP-1(7-37), GLP-1 (7-36)amide, exendin-3, and exendin-4.

### **Maintained Formal Matters, Objections, and/or Rejections:**

Claims 26-29, 36-72 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of lowering plasma levels of triglycerides, free

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fatty acids, or total cholesterol, does not reasonably provide enablement for a method of lowering one or more serum lipids, of reducing the serum LDL:HDL ratio, or of reducing the serum level of lp(A) or apo(A).

The examiner also relies on Vilsboll (date not provided by applicants). Vilsboll teaches  
5 that there was not differences in total cholesterol, HDL, LDL, or ApoB between liraglutide groups and placebo. Vilsboll provides further objective evidence that the full scope of the claims has not been enabled.

***Response to Appeal Brief***

The examiner has already responded to the appeal brief filed 01/03/2005. See the  
10 examiner's answer mailed 04/05/2005.

***Response to Reply Brief***

Applicants argue that the examiner has no stated basis for rejecting claims directing to lowering one or more serum lipids or reducing the serum level of lp(A) or apo(A) for lack of enablement. Applicants' arguments have been fully considered but they are not persuasive. The  
15 only working examples in the specification show lowering plasma levels of triglycerides, free fatty acids, or total cholesterol. Juntti-Berggren (Diabetes Care. 1996 Nov;19(11):1200-6) observed no changes in the levels of LDL and HDL cholesterol after administration of GLP-1 (page 1200, "RESULTS"). This is objective evidence that the full scope of the claims is not enabled. This evidence also provides a reason to doubt the objective truth of statements in the  
20 specification.

Applicants argue that the examiner has not established that the LDL:HDL ratio in Juntti-Berggren's subjects was outside the normal range. Applicants' arguments regarding "no reason

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to expect that it would change,” “single protocol,” “limited number,” “optimization,” “drug interactions,” and “length” are acknowledged. Applicants’ arguments have been fully considered but they are not persuasive. Applicants’ arguments are mere argument. Arguments of counsel cannot take the place of evidence in the record.

5 Applicants argue that applicants are under no obligation to present any experimental data. Applicants’ arguments have been fully considered but they are not persuasive. Although the examiner stated “Appellants have not presented any experimental data ...,” the examiner did not mean to say that applicants must present experimental data. The examiner meant to say that applicants have not presented any objective evidence that that a single protocol, the patients’  
10 medical history, physical condition, activity, or regular diet, is correlated with the observed lack of changes in the levels of LDL and HDL cholesterol after administration of GLP-1. Furthermore, the specification envisions the treatment of diabetic patients with a GLP analog in combination with insulin and insulin sensitizers.

15 Claims 26-29, 36-72 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

20 The examiner also relies on Vilsboll (date not provided by applicants). Vilsboll teaches that there was not differences in total cholesterol, HDL, LDL, or ApoB between liraglutide

groups and placebo. Vilsboll provides further objective evidence that the full scope of the claims has not been described.

***Response to Appeal Brief***

The examiner has already responded to the appeal brief filed 01/03/2005. See the  
5 examiner's answer mailed 04/05/2005.

***Response to Reply Brief***

Applicants argue that the examiner has no stated basis for rejecting claims directing to lowering one or more serum lipids or reducing the serum level of lp(A) or apo(A) for lack of enablement. Applicants' arguments have been fully considered but they are not persuasive. The  
10 only working examples in the specification show lowering plasma levels of triglycerides, free fatty acids, or total cholesterol. Juntti-Berggren (Diabetes Care. 1996 Nov;19(11):1200-6) observed no changes in the levels of LDL and HDL cholesterol after administration of GLP-1 (page 1200, "RESULTS"). This is objective evidence that the full scope of the claims is not described. This evidence also provides a reason to doubt the objective truth of statements in the  
15 specification.

Applicants argue that the examiner has not established that the LDL:HDL ratio in Juntti-Berggren's subjects was outside the normal range. Applicants' arguments regarding "no reason to expect that it would change," "single protocol," "limited number," "optimization," "drug interactions," and "length" are acknowledged. Applicants' arguments have been fully  
20 considered but they are not persuasive. Applicants' arguments are mere argument. Arguments of counsel cannot take the place of evidence in the record.

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Applicants argue that applicants are under no obligation to present any experimental data. Applicants' arguments have been fully considered but they are not persuasive. Although the examiner stated "Appellants have not presented any experimental data ...," the examiner did not mean to say that applicants must present experimental data. The examiner meant to say that applicants have not presented any objective evidence that that a single protocol, the patients' medical history, physical condition, activity, or regular diet, is correlated with the observed lack of changes in the levels of LDL and HDL cholesterol after administration of GLP-1. Furthermore, the specification envisions the treatment of diabetic patients with a GLP analog in combination with insulin and insulin sensitizers.

Claims 26, 27, 29, 36, 37, 39, 40, 42, 44-49, 52, 54-59, 62, 64-69, 72-73, and 76 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

***Response to Appeal Brief***

The examiner has already responded to the appeal brief filed 01/03/2005. See the examiner's answer mailed 04/05/2005.

***Response to Reply Brief***

Applicants argue that the specification provides sufficient written description to show possession. Applicants' arguments have been fully considered but they are not persuasive. The claims are directed to or encompass a genus of compounds that are GLP-1 agonists, wherein the

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agonist is an “analogue,” “derivative,” or “derivative of an analogue” of the specific GLP-1 agonists recited in the present claims. The specification and claim do not indicate what distinguishing attributes shared by the members of the genus. The specification and claim do not place any structural limitations on the structure of the agonist. Thus, the scope of the claim includes numerous structural variants, and the genus is highly variant because there are no structural limitations to the genus. No common structural attributes identify the members of the genus. Accordingly, there is no correlation of the structure of the genus with the function of the genus. The disclosed species are not representative of the scope because there are structural limitations to the an “analogue,” “derivative,” or “derivative of an analogue” of the specific GLP-1 agonists recited in the present claims.

Claims 44-49, 52, 54-59, 62, 64-69, 72-73, and 76 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

***Response to Appeal Brief***

The examiner has already responded to the appeal brief filed 01/03/2005. See the examiner’s answer mailed 04/05/2005.

***Response to Reply Brief***

Applicants argue that the specification provides definitions for the terms “derivative” and “analog” and that the examples fall within these definitions. Applicants’ arguments have been fully considered but they are not persuasive. It is apparent that there is no correlation between the structure of the “analogue,” “derivative,” or “derivative of an analogue” recited in the present



claims and the specific examples of a GLP-1 agonist or derivative disclosed in the present specification because there is no structure associated with the “analogue,” “derivative,” or “derivative of an analogue” recited in the present claims. Therefore, Appellants’ reliance on the specific examples of such compounds to describe the genus is inadequate.

5 **New Formal Matters, Objections, and/or Rejections:**

***Claim Rejections - 35 USC § 102***

Claims 26–29, 36–42, 44, 46, 48, 51–52, 54, 56, 58, 61–62, 64, 66, 68, 71–74, and 76 are rejected under 35 U.S.C. 102(b) as being anticipated by Beeley (WO 98/30231).

The relevant passages from Beeley are as follows:

- 10 In those few subjects who do succeed in losing weight, by about 10 percent of body weight, there can be striking improvements in co-morbid conditions, most especially Type 2 diabetes in which dieting and weight loss are the primary therapeutic modality, albeit relatively ineffective in many patients for the reasons stated above. Reducing food intake in obese subjects would decrease the plasma glucose level, the plasma lipid level, and the cardiac risk in these subjects. Paragraph bridging pages 7-8.
- 15
- 20 The present invention is directed to novel methods for treating conditions or disorders associated with hypernutrition, comprising the administration of an exendin, for example, exendin-3 or exendin-4, or other compounds which effectively bind to the receptor at which exendin exerts its action on reducing food intake. These methods will be useful in the treatment of, for example, obesity, diabetes, including Type II or non-insulin dependent diabetes, eating disorders, and insulin-resistance syndrome. Paragraph bridging pages 8-9.
- 25 Thus, in a first embodiment, the present invention provides a method for treating conditions or disorders which can be alleviated by reducing food intake in a subject comprising administering to said subject a therapeutically effective amount of an exendin or an exendin agonist. Page 10, full paragraph 1.
- 30 In various preferred embodiments of the invention, the condition or disorder is obesity, diabetes, preferably Type II diabetes, an eating disorder, or insulin-resistance syndrome. Page 11, full paragraph 1.

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In yet other preferred aspects, a method is provided for lowering plasma lipids comprising administering to said subject a therapeutically effective amount of an exendin or an exendin agonist. Page 11, full paragraph 3.

5 The methods of the present invention may also be used to reduce the cardiac risk of a subject comprising administering to said subject a therapeutically effective amount of an exendin or an exendin agonist. Paragraph bridging pages 11-12.

10 In other embodiments of the invention is provided a pharmaceutical composition for use in the treatment of conditions or disorders which can be alleviated by reducing food intake comprising a therapeutically effective amount of an exendin or exendin agonist in association with a pharmaceutically acceptable carrier. Preferably, the pharmaceutical composition comprises a therapeutically effective amount for a human subject. The  
15 pharmaceutical composition may preferably be used for reducing the appetite of a subject, reducing the weight of a subject, lowering the plasma lipid level of a subject, or reducing the cardiac risk of a subject. Those of skill in the art will recognize that the pharmaceutical composition will preferably comprise a therapeutically effective amount of an exendin or exendin agonist to accomplish the desired effect in the subject. Page 13,  
20 full paragraphs 1-2.

Accordingly, Beeley teaches a method for lowering plasma lipids or reducing cardiac risk comprising administering to a subject afflicted with obesity and type 2 diabetes a therapeutically effective amount of an exendin or an exendin agonist. The present claims are directed to or encompass administering to a patient in need of having one or more serum lipid levels lowered  
25 an effective amount of a GLP-1 agonist, or wherein the patient suffers from a disease state that is alleviated by lowering serum levels of said one or more lipids. The present specification discloses that the invention is useful for treating diseases that may be alleviated by lowering serum lipid levels, including, e.g., cardiovascular disease and diabetes (Abstract). Accordingly, Beeley discloses the administration of the same or substantially the same compounds as used in  
30 the presently claimed methods to subjects that are encompassed by the patients administered to in the present claims. Furthermore, newly discovered results of known or obvious processes directed to the same purpose are not patentable because such results are either inherent or would

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naturally flow from following the teachings, suggestions, or motivations of the prior art. The recitation of an additional advantage associated with doing what Beeley teaches does not lend patentability to an otherwise unpatentable invention. Furthermore, a chemical composition and its properties are inseparable. Therefore, the properties applicant discloses and/or claims are  
5 necessarily present in Beeley's exendin or exendin agonist.

Claims 26–27, 29, 36–37, 39–40, 42–43, 46, 48, 52–54, 56, 58, 62–64, 66, 68, 72–73, and 76 are rejected under 35 U.S.C. 102(b) as being anticipated by Juntti-Berggren (Diabetes Care. 1996 Nov;19(11):1200-6).

10 Juntti-Berggren discloses that dyslipoproteinemia is a common feature of patients with NIDDM and that treatment of the diabetic state leads to improvement of the plasma lipoprotein profile (page 1200, right column, full paragraph 2). Juntti-Berggren treated NIDDM patients with GLP-1 (GLP-1(7–36)amide) for one week (paragraph bridging pages 1200-1201).

The present claims are directed to or encompass administering to a patient in need of  
15 having one or more serum lipid levels lowered an effective amount of a GLP-1 agonist, or wherein the patient suffers from a disease state that is alleviated by lowering serum levels of said one or more lipids. The present specification discloses that the invention is useful for treating diseases that may be alleviated by lowering serum lipid levels, including, e.g., cardiovascular disease and diabetes (Abstract). Accordingly, Juntti-Berggren discloses the administration of the  
20 same or substantially the same compounds as used in the presently claimed methods to subjects that are encompassed by the patients administered to in the present claims. Furthermore, newly discovered results of known or obvious processes directed to the same purpose are not patentable

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because such results are either inherent or would naturally flow from following the teachings, suggestions, or motivations of the prior art. The recitation of an additional advantage associated with doing what Juntti-Berggren teaches does not lend patentability to an otherwise unpatentable invention. Furthermore, a chemical composition and its properties are inseparable. Therefore, the properties applicant discloses and/or claims are necessarily present in Juntti-Berggren's GLP-1.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 26–29, 36–42, 44, 46, 48, 51–52, 54, 56, 58, 61–62, 64, 66, 68, 71–74, and 76

rejected under 35 U.S.C. 103(a) as being unpatentable over Beeley (WO 98/30231).

This rejection is being made in the event that the rejection of claims 26–29, 36–42, 44, 46, 48, 51–52, 54, 56, 58, 61–62, 64, 66, 68, 71–74, and 76 under 35 U.S.C. 102(b) as being anticipated by Beeley (WO 98/30231) is overcome.

The teachings of Beeley are discussed above. It would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to administer an exendin or exendin agonists, as taught by Beeley, to a patient in need of having one more serum lipid levels lowered or wherein said patient suffers from a disease state that is alleviated by lowering serum lipid levels, with a reasonable expectation of success. One of ordinary skill in the art would be motivated to make this modification because an exendin or exendin agonist lowers plasma lipid

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levels. Furthermore, newly discovered results of known or obvious processes directed to the same purpose are not patentable because such results are either inherent or would naturally flow from following the teachings, suggestions, or motivations of the prior art.

5           Claims 29–29, 36–42, 44–50, 52, 54–60, 62, 64–70, 72–74, and 76 rejected under 35 U.S.C. 103(a) as being unpatentable over Beeley (WO 98/30231) as applied to claims 26–29, 36–42, 44, 46, 48, 51–52, 54, 56, 58, 61–62, 64, 66, 68, 71–74, and 76 above or Juntti-Berggren (Diabetes Care. 1996 Nov;19(11):1200-6) as applied to claims 26–27, 29, 36–37, 39–40, 42–43, 46, 48, 52–54, 56, 58, 62–64, 66, 68, 72–73, and 76, and further in view of Knudsen (WO  
10 98/08871).

Beeley teaches the administration of an exendin or exendin agonist, as discussed above.

Juntti-Berggren teaches GLP-1(7-36) amide, as discussed above.

Beeley or Juntti-Berggren do not teach the administration of Arg<sup>34</sup>,Lys<sup>26</sup>(N<sup>ε</sup>-(γ-Glu(N<sup>α</sup>-hexadecanoyl)))GLP-1(7-37).

15           Knudsen (WO 98/08871) teaches GLP-1 analogs having a more protracted profile of action than GLP-1(7-37) (Abstract), wherein the GLP-1 analog is Arg<sup>34</sup>,Lys<sup>26</sup>(N<sup>ε</sup>-(γ-Glu(N<sup>α</sup>-hexadecanoyl)))GLP-1(7-37) (page 56, Example 37). Knudsen is silent with respect to the lowering of serum lipid levels.

20           However, it would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to administer an exendin or exendin agonist, as taught by Beeley, or GLP-1(7-36) amide, as taught by Juntti-Berggren, with a reasonable expectation of success. One of ordinary skill in the art would be motivated to make this modification because Arg<sup>34</sup>,Lys<sup>26</sup>(N<sup>ε</sup>-(γ-

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Glu(N<sup>α</sup>-hexadecanoyl)))GLP-1(7-37) has a more protracted profile of action. The invention is prima facie obvious over the prior art.

***Double Patenting***

Claims 26-29, 36-42, 44-50, 52, 54-60, 62, 64-70, 72-73, and 76 are rejected under the  
5 judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 39, 40 of U.S. Patent No. 6,268,343 in view of Beeley (WO 98/30231).

The patent claims teach a method treating diabetes or obesity comprising administering GLP-1 analogs in general and Arg<sup>34</sup>,Lys<sup>26</sup>(N<sup>ε</sup>-(γ-Glu(N<sup>α</sup>-hexadecanoyl)))GLP-1(7-37) in particular. The patent claims are silent with respect to lowering lipid levels. Beeley teaches a  
10 method for lowering plasma lipids or reducing cardiac risk comprising administering to a subject afflicted with obesity and type 2 diabetes a therapeutically effective amount of an exendin or an exendin agonist. It would have been obvious to one of ordinary skill in the art at the time of Applicants' invention that a method of treating obesity or diabetes with a GLP-1 analog is a method of lowering plasma lipid levels.

15

Claims 26-29, 36-42, 44-50, 52, 54-60, 62, 64-70, 72-73 and 76 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19, 20 of U. S. Patent No. 6,458,924 in view of Beeley (WO 98/30231).

The patent claims teach a method treating diabetes or obesity comprising administering  
20 GLP-1 analogs in general and Arg<sup>34</sup>,Lys<sup>26</sup>(N<sup>ε</sup>-(γ-Glu(N<sup>α</sup>-hexadecanoyl)))GLP-1(7-37) in particular. The patent claims are silent with respect to lowering lipid levels. Beeley teaches a method for lowering plasma lipids or reducing cardiac risk comprising administering to a subject

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afflicted with obesity and type 2 diabetes a therapeutically effective amount of an exendin or an exendin agonist. It would have been obvious to one of ordinary skill in the art at the time of Applicants' invention that a method of treating obesity or diabetes with a GLP-1 analog is a method of lowering plasma lipid levels.

5

***Claim Objections***

Claim 74 is objected to because of the following informalities: Arg<sup>34</sup>,Lys<sup>26</sup>(N<sup>ε</sup>-(γ-Glu(N<sup>α</sup>-hexadecanoyl)))GLP-1(7-37) is misspelled. Appropriate correction is required.

***Conclusion***

No claims are allowable.

10

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Ferris (Diabetes Care. 1996 Nov;19(11):1291-3) teaches that lowering elevated serum lipids may help reduce the risk of vision loss for patients with diabetic retinopathy (page 1291, left column, full paragraph 1).

15

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (571) 272-0890. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M. IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, BRENDA BRUMBACK, CAN BE REACHED ON (571) 272-0961.

20

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE CENTRAL FAX NUMBER FOR OFFICIAL CORRESPONDENCE, WHICH IS (571) 273-8300.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

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DAVID ROMEO  
PRIMARY EXAMINER  
ART UNIT 1647